

REMARKS

I. Status of the Application

Claims 1-39 are presently pending in the application. Claims 8-26 and 36 have been withdrawn by the Examiner. Claims 4, 5, and 6 have been cancelled without prejudice to the filing of any appropriate continuation application and subject matter of claims 4, 5, and 6 has been included into claim 1. Claim 1 has been amended to recite a thermoplastic polymer. Support for the amendment is provided at page 11, line 15 and at page 15, line 3 of the published application WO 2004/039424.

Claims 1-5, 28, 32 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hahn US 5,129,889. Claim 35 stands rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Hahn.

Claims 1-7, 27, 28, 33-35, and 37 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546. Claims 29 and 30 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546 and further in view of Noda US 6,669,711. Claims 29 and 30 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546 and further in view of Bays US 4,650,488. Claim 39 stands rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546 and Bays US 4,650,488 and further in view Martin US 5,017,188.

Applicants respectfully request reconsideration of the foregoing claims in view of the amendments and remarks.

II. The Rejections Based on Hahn

At page 3 of the present office action, claims 1-5, 28, 32 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hahn US 5,129,889. At page 4 of the present office action, claim 35 stands rejected under 35 U.S.C. § 102(b) as being anticipated by, or under 35 U.S.C. §103(a) as being obvious over Hahn US 5,129,889. Applicants respectfully traverse the rejection for reasons of record as presented in applicants' response filed May 19, 2010. However, solely to expedite prosecution, applicants have amended claim 1 and claim 35 to include the subject matter of claim 6. Claim 6 does not stand rejected as being either anticipated or obvious over Hahn alone or in combination with a secondary reference. Accordingly, applicants respectfully submit that the amendment to claims 1 and 35 has obviated the Examiner's rejection.

III. Claims 1-7, 27, 28, 33-35 and 37 Are Not Obvious Over Amsden and Grieshaber

At page 6 of the present office action, claims 1-7, 27, 28, 33-35, and 37 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

Claim 1 has been amended to recite a thermoplastic polymer so as to distinguish the claimed polymer from crosslinked polymers. The specification teaches at page 15 lines 3-18 that drains according to the present invention can be made from thermoplastic polymers by dissolving the thermoplastic polymer in a solute followed by dip-coating or spray coating methods. Because thermoplastic polymers are used, the thickness of the drains can be regulated

using the dip-coating and spray coating methods. This aspect of the present invention is claimed by claim 35.

Amsden, which is directed to thermally crosslinked and photo-crosslinked polymers, fails to teach or suggest drains having thermoplastic polymers as claimed. Grieshaber, relied upon for the teaching of a drain, fails to cure the deficiencies of Amsden.

Amsden is very clearly directed to the formation of a crosslinked polymer. For example, at page 1 paragraphs 6, 7, and 8, the invention of Amsden is summarized as follows:

In accordance with one aspect of the invention there is provided a method of preparing a thermally crosslinked biodegradable/biocompatible elastomeric polymer comprising: combining a star co-polymer with a bislactone crosslinking agent, and heating the combined star co-polymer and crosslinking agent, so that a crosslinked biodegradable/biocompatible elastomeric polymer is prepared.

In accordance with another aspect of the invention there is provided a method of preparing a photo-crosslinked biodegradable/biocompatible elastomeric polymer comprising: combining a photo-crosslinkable star co-polymer with an initiator, and exposing the combined photo-crosslinkable star copolymer and initiator to photo-crosslinking light, so that a crosslinked biodegradable/biocompatible elastomeric polymer is prepared.

The invention further provides a thermally crosslinked biodegradable/biocompatible elastomeric polymer, and a photo-crosslinked biodegradable/biocompatible elastomeric polymer.

Amsden provides no teaching of a thermoplastic polymer and Amsden only teaches polymers that are thermally crosslinked or photo-crosslinked. In addition, the Examiner acknowledges that Amsden fails to teach or suggest a drain, and especially a drain formed from a thermoplastic polymer as claimed.

Further, Amsden fails to teach a thermoplastic polymer with an elastic modulus of less than 120MPa. The Examiner believes that Grieshaber teaches a tube, but there is no teaching that the tube is formed from a thermoplastic polymer as claimed or having an elastic modulus of less than 120MPa. Applicants respectfully submit that the recitation of a thermoplastic polymer

as now claimed provides additional structural characteristics distinguishing the claimed polymer from that of the prior art such that one of skill would not reasonably expect the prior art polymers to exhibit the claimed elastic modulus. *In re Fitzgerald* does not apply. There are no facts of record on which the Examiner can conclude that the polymer of Amsden has the claimed elastic modulus. It is just as likely that the polymer of Amsden may have a completely different elastic modulus.

In addition, the tube of Grieshaber is not biodegradable, but is intended to be permanently left inside an individual as a structural support element. The biodegradable drain of the pending application is intended to be left inside the body for an extended period of time, specifically to “remain functional in the body or antrum orifice for the duration of the prescribed, clinical appropriate period of time to accomplish the predetermined therapeutic purpose.” See page 5, lines 7-9 of the pending application. In fact, the drains are intended to maintain their functional properties for 2 to 12 weeks or in some situations for several months. See page 16, lines 13-15 and page 17, lines 22-24. This is not true with the tube of Grieshaber.

Since the Examiner’s combination of Amsden and Grieshaber fails to teach all of the claim limitations of the amended claims now presented, the combination of Amsden and Grieshaber does not create a *prima facie* case of obviousness.

IV. Claims 29 and 30 Are Not Obvious Over Amsden, Grieshaber and Noda

At page 8 of the present office action, claims 29 and 30 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden, Grieshaber and Noda US 6,669,711. Applicants respectfully traverse the Examiner’s rejection as to the amended claims now presented.

For the reasons discussed above, the combination of Amsden and Grieshaber fails to teach or suggest all of the limitations of claims 29 and 30. Noda, which is relied upon for the teaching of a nasal drain, fails to cure the deficiencies of Amsden and Grieshaber. Further, one of skill in the art of biodegradable drains would not look to Noda because Noda discloses a surgical balloon that “prevents a liquid or gas from flowing from one area of the body to another area.” See col. 2, lines 49-52. This is the opposite desired effect of the disclosed drain. Accordingly, applicants respectfully request that the rejection of claims 29 and 30 based on Amsden, Grieshaber and Noda be withdrawn.

V. Claims 37 and 38 Are Not Obvious Over Amsden, Grieshaber and Bays

At page 9 of the present office action, claims 37 and 38 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden, Grieshaber and Bays US 4,650,488. Applicants respectfully traverse the Examiner’s rejection as to the amended claims now presented.

For the reasons discussed above, the combination of Amsden and Grieshaber fails to teach or suggest all of the limitations of claims 37 and 38. Bays fails to cure the deficiencies of Amsden and Grieshaber. Accordingly, applicants respectfully request that the rejection of claims 37 and 38 based on Amsden, Grieshaber and Bays be withdrawn.

VI. Claim 39 Is Not Obvious Over Amsden, Grieshaber, Bays and Marten

At page 9 of the present office action, claim 39 stands rejected under 35 U.S.C. § 103(a) as being obvious over Amsden, Grieshaber, Bays and Marten US 5,017,188. Applicants respectfully traverse the Examiner’s rejection as to the amended claims now presented.

For the reasons discussed above, the combination of Amsden, Grieshaber and Bays fails to teach or suggest all of the limitations of claim 39. Marten fails to cure the deficiencies of Amsden, Grieshaber and Bays. Accordingly, applicants respectfully request that the rejection of claim 39 based on Amsden, Grieshaber, Bays and Marten be withdrawn.

VII. Conclusion

Having addressed all outstanding issues, applicants respectfully request reconsideration and allowance of this case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below. The Commissioner is authorized to apply any additional charges or credits to Deposit Account No. 19-0733.

Respectfully submitted,

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